K130346

MAY 2 2013

~~510~~(k) Summary
Synergy Focus

[A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92]

1. Submitter / 510(k) Holder

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Date prepared	March 5, 2013

2. Device Name

Proprietary name	Natus Synergy Focus	
Common name	Diagnostic Electromyograph	
Device Class	Class II	
Classification name	Evoked Response Electrical Stimulator (Primary) Diagnostic Electromyograph Nerve Conduction Velocity Measurement Device Non-normalizing Quantitative Electroencephalograph Software Evoked Response Auditory Stimulator Evoked Response Photic Stimulator Evoked Response Mechanical Stimulator	
Product Code, Regulation	GWF	21 CFR §882.1870 (Primary)
	JXE	21 CFR §882.1550
	IKN	21 CFR §890.1375
	OLT	21 CFR §882.1400
	GWJ	21 CRF §882.1900
	GWE	21 CFR §882.1890
	GZP	21 CFR §882.1880

3. Predicate Devices

510(K) Number	Device Name
K112052	CareFusion Nicolet EDX with Viking Software
K120979	CareFusion Nicolet EDX with Synergy Software

4. Device Description

The Natus Synergy Focus (Synergy Focus) is designed for the acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular systems. The system is designed to perform nerve conduction studies (NCS), needle electromyography (EMG) testing, evoked potential (EP) testing, and intra-operative monitoring (IOM). Synergy Focus provides a variety of tests spanning the various modalities.

The Synergy Focus consists of the following major components:

- Console base unit with integrated control panel;
- Amplifier (with three non-switched amplifier channels);
- Desktop or laptop computer with a keyboard and mouse;
- Display monitor; and
- Synergy Software

The Synergy Focus optional accessories/components consists of the following:

- Stimulator probes (RS 10 probe, Stimulus Probe with controls)
- Footswitches (triple)
- LED goggles
- Headphones or other auditory transducers
- Patient response button
- Cart
- Isolation transformer
- Printer

Description of Major Components

Console Base with integrated control panel:
The console base is an AC mains powered electrical device that houses the core hardware, and provides interconnection capability with the rest of the Natus hardware and PC. This is equivalent hardware base as in the Nicolet EDX with Viking or Synergy software system. The PC contains the software.

The control panel along with the mouse is the primary user interface for the Synergy Focus system. The control panel contains a variety of controls that allow the user to access and use the Synergy Focus system from the touch of a button or knob. This control panel performs similar functions as the Viking or Synergy control panels from the Nicolet EDX with Viking or Synergy software system.

Amplifier:
The amplifier is a DC powered electrical device that records, amplifies and transmits responses from the nerve and/or muscle to the console base. The amplifier collects up to three channels of neurophysiological information. This is equivalent to the amplifiers in the Nicolet EDX with Viking or Synergy software system.

Personal Computer (PC) with Keyboard and Mouse:
The Synergy Focus system hardware is used in conjunction with a personal computer (PC), which is offered in either a desktop or laptop configuration. These are exactly the same PCs as in the Nicolet EDX with Viking or Synergy software system. The Synergy software is supplied preloaded onto the PC.

Display Monitor:
The desktop PC version requires a display monitor which is provided with the Synergy Focus system hardware. The laptop version does not require a separate display monitor beyond the built-in laptop display; however, an external display monitor may be used if desired. The additional display monitor is facilitated through the connection to an isolation transformer that is included with a desktop PC and available as an optional accessory for laptop based systems. These are exactly the same monitors and isolation transformer as in the Nicolet EDX with Viking or Synergy software system.

Description of Optional Accessory Components

Electrical Stimulator Probes:
There are two types of electrical stimulator probes available for use with the Synergy Focus System Hardware: (1) the RS 10 Comfort Probe and (2) Stimulus Probe with controls. The RS 10 Comfort Probe is exactly the same Stimulus Probe as in the Nicolet EDX with Viking or Synergy software system. The Stimulus Probe with controls is equivalent to the WR50 Comfort Plus Probe in the Nicolet EDS with Viking or Synergy Software system. The probes connect to the console base via a cable. Each probe contains a tip that facilitates direct stimulus contact to the patient when activated. The probes can deliver a stimulus ranging from 0 - 100 mA.

Triple Footswitch:
The footswitches allow the user to activate defined functions such as electrical stimulation and initiate acquisition of trace data. Pressing the footswitch activates or deactivates the user defined function. This is exactly the same footswitch with identical functions as in the Nicolet EDX with Viking or Synergy software system.

LED Goggles:
LED goggles are available to provide visual stimulation to the patient when the Visual Evoked Potential (VEP) software option is in use. These goggles are equivalent to the LED goggles and function as in the Nicolet EDX with Viking or Synergy software system.

Headphones or other Auditory Transducers:
Headphones are available, or other auditory transducers may be used to provide auditory stimulation to the patient through the transducer when the Auditory Evoked Potential (AEP) is in use. Headphones and transducers have no controls or indicators and are connected to the Console Base unit auditory stimulator output connectors. These are equivalent to the transducers and function as in the Nicolet EDX with Viking or Synergy software system.

Patient Response Button:

The patient response button allows the patient to respond to a rare stimulus during specific EP testing. This is exactly the same Patient Response Button and function as in the Nicolet EDX with Viking software system. The patient presses the button when the rare stimulus is detected. The

Nicolet EDX senses the button press and increments a count.

Cart and Printer:
The metal cart provides a convenient way to contain all of the components of the Synergy Focus System Hardware into one mobile location. The cart has lockable wheels and a convenient handle to facilitate movement of the cart. Two articulating arms are provided for mounting the display monitor and amplifier. There are multiple shelves present to accommodate the placement and storage of various Natus System Hardware components and supplies. A retractable keyboard shelf and mouse pad is available. In terms of printing capabilities, a printer equivalent to a DeskJet or Laser printer is available for connection to the system to print reports or screen copies. The cart is exactly the same and functions the same as in the Nicolet EDX with Viking or Synergy software system.

5. Indications for Use:

The Synergy Focus is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Synergy Focus may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Synergy Focus is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Synergy Focus is intended to be used by a qualified healthcare provider.

6 Summary of Technical Characteristics Compared to the Predicate Devices

1. General – Indications				
Characteristic	**Natus Neurology, Inc. Synergy Focus (this submission)**	**CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
1.1 Indications for Use	The Synergy Focus is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP) Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Synergy Focus may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Synergy Focus is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Synergy Focus is intended to be used by a qualified healthcare provider.	The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Nicolet EDX with Synergy Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Synergy Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Nicolet EDX with Synergy Software is intended to be used by a qualified healthcare provider.	The CareFusion Nicolet EDX is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG). Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, and Motor Evoked Potentials (MEP). The Nicolet EDX with Synergy Software may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Nicolet EDX with Synergy Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition. The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System. The Nicolet EDX with Viking Software is intended to be used by a qualified healthcare provider.	Identical to the Nicolet EDX with Viking and Synergy software.

1.2 Warnings	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Items related to off-label use or misuse.	Identical to the Nicolet EDX with Viking or Synergy software.
1.3 Contra-indications	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Identical to the Nicolet EDX with Viking or Synergy software

2.General Design				
Characteristic	**Natus Neurology, Inc. Synergy Focus (this submission)**	**CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
2.1 General systems approach	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Computer based equipment with dedicated hardware peripherals / components.	Identical to the Nicolet EDX with Viking or Synergy software
2.2 User input device	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Identical to the Nicolet EDX with Viking or Synergy software
2.3 User output device	Digital color display and commercial printers	Digital color display and commercial printers	Digital color display and commercial printers	Identical to the Nicolet EDX with Viking or Synergy software
2.4 Patient inputs	1 to 3 channel amplifier, isolated	2 to 8 channel amplifier, isolated	2 to 8 channel amplifier, isolated	Subset of the Nicolet EDX with Viking or Synergy software
2.5 Signal acquisition	Analog to digital conversion at 48kHz sample rate	Analog to digital conversion at 48kHz sample rate	Analog to digital conversion at 48kHz sample rate	Identical to the Nicolet EDX with Viking or Synergy software
2.6 Trigger input (synchronization to external events)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
2.7 Trigger output (synchronization for external devices)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
2.8 Footswitch for hands-free operation	Yes	Yes	Yes	Triple footswitch only, identical to the triple footswitch in the Nicolet EDX with Viking or Synergy software
2.9 Use of standard software platform (Operating System)	Yes Microsoft Windows	Yes Microsoft Windows	Yes Microsoft Windows	Identical to the Nicolet EDX with Viking or Synergy software
2.10 Customization of protocols	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Identical to the Nicolet EDX with Viking or Synergy software
2.11 Application flexibility / expandability	Via software update	Via software update	Via software update	Identical to the Nicolet EDX with Viking or Synergy software
2.12 Safety Standards	EN/IEC 60601-1:1988 + A1:1991+A2:1995, IEC 60601-1-1:2000 EN/IEC 60601-1-2: Ed. 2.0+A1:2004	EN/IEC 60601-1:1998 + A1:1991+A2:1995, IEC 60601-1-1:2000 EN/IEC 60601-1-2: Ed. 2.0+A1:2004	EN/IEC 60601-1:1998 + A1:1991+A2:1995, IEC 60601-1-1:2000 EN/IEC 60601-1-2: Ed. 2.0+A1:2004	Identical to the Nicolet EDX with Viking or Synergy software

	IEC 60601-2-40: 1998, Ed:1, ISO 10993-1:2009 ISO 14971-2007	IEC 60601-2-40: 1998, Ed:1, ISO 10993-1:2009 ISO 14971-2007	IEC 60601-2-40: 1998, Ed:1, ISO 10993-1:2009 ISO 14971-2007	
2.13 Patient circuitry isolation	Optic/transformer	Optic/transformer	Optic/transformer	Identical to the Nicolet EDX with Viking or Synergy software
2.14 System components	Base console including 1 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	EDX base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	EDX base console including 2 electrical stimulators, auditory stimulator, trigger input/output, LED goggle interface; Control panel; Amplifier; Computer, monitor, keyboard, mouse, printer	Equivalent to the Nicolet EDX with Viking or Synergy software with only 1 electrical stimulator
2.15 System – computer interface	USB	USB	USB	Identical to the Nicolet EDX with Viking or Synergy software
2.16 System power supply	Mains (100 – 240 VAC) thru an isolation transformer	Mains (100 – 240 VAC) thru an isolation transformer	Mains (110 – 240 VAC) thru an isolation transformer	Identical to the Nicolet EDX with Viking or Synergy software
2.17 Amplifier power supply	15 VDC from base console	15 VDC from base console	15 VDC from base console	Identical to the Nicolet EDX with Viking or Synergy software
2.18 Size (L/W/D) cm	39.3 x 34.2 x 7.6 cm (base console)	35.6 x 34.3 x 8.6 cm (base console)	35.6 x 34.3 x 8.6 cm (base console)	Similar in size to the Nicolet EDX with Viking or Synergy software
2.19 Weight kg	3.3 kg (base console)	3.5kg (base console)	3.5 kg (base console)	Similar in weight to the Nicolet EDX with Viking or Synergy software

Footnote 1: The Synergy Focus control panel is functionally equivalent to the Viking and Synergy control panels but the number of controls differs.

3. Design - Acquisition				
Characteristic	**Natus Neurology, Inc. Synergy Focus (this submission)**	**CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
3.1 Number of channels	1 to 3	2 to 8	2 to 8	Identical to the Nicolet EDX with Viking or Synergy software
3.2 CMRR	> 110 dB	> 110 dB	> 110 dB	Identical to the Nicolet EDX with Viking or Synergy software
3.3 Noise	< 0.4uV RMS (from 2 Hz to 10 kHz)	< 0.6uV RMS (from 2 Hz to 10 kHz)	< 0.6uV RMS (from 2 Hz to 10 kHz)	Slightly better noise than the Nicolet EDX with Viking or Synergy software
3.4 Input impedance	>1000 MΩ	>1000 MΩ	>1000 MΩ	Identical to the Nicolet EDX with Viking or Synergy software
3.5 Low Filter	0.05 Hz to 5 kHz	0.05 Hz to 5 kHz	0.05 Hz to 5 kHz	Identical to the Nicolet EDX with Viking or Synergy software
3.6 High filter	30 Hz to 20 kHz	30 Hz to 20 kHz	30 Hz to 20 kHz	Identical to the Nicolet EDX with Viking or Synergy software
3.7 Notch filter	50 / 60 selectable	50 / 60 selectable	50 / 60 selectable	Identical to the Nicolet EDX with Viking or Synergy software
3.8 A/D conversion	24 bit	24 bit	24 bit	Identical to the Nicolet EDX with Viking or Synergy software
3.9 Sampling rate (cumulative)	144 kHz	384 kHz	384 kHz	Per channel sample rate of 48 kHz is identical to the Nicolet EDX with Viking or Synergy software
3.10 Time base range	0.01 to 5000 ms	0.01 to 5000 ms	0.01 to 5000 ms	Identical to the Nicolet EDX with Viking or Synergy software
3.11 Number of Time bases allowed	Multiple	Multiple	Multiple	Identical to the Nicolet EDX with Viking or Synergy software
3.12 Trigger mode	Free run, internal, external	Free run, internal, external	Free run, internal, external	Identical to the Nicolet EDX with Viking or Synergy software
3.13 Signal delay (pre/post)	-3000 to +500 ms	-3000 to +500 ms	-3000 to +500 ms	Identical to the Nicolet EDX with Viking or Synergy software
3.14 Impedance meter	1 kΩ to 1,000 kΩ	500 Ω to 480 kΩ	500 Ω to 480 kΩ	Able to measure higher electrode impedance than the Nicolet EDX with Viking or Synergy software

4. Design - Stimulators				
Characteristic	**Natus Neurology, Inc. Synergy Focus (this submission)**	**CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
4.1 Electrical Stimulator				
4.1.1 Type	Constant Current	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Identical to the Nicolet EDX with Viking or Synergy software, only constant current
4.1.2 Number	1	1 or 2	1 or 2	Identical to the Nicolet EDX with Viking or Synergy software with only 1 stimulator
4.1.3 Maximum Output	100mA	100mA or 400V	100mA or 400V	Identical to the Nicolet EDX with Viking or Synergy software, only constant current
4.1.4 Duration	0.01 to 1 ms	0.01 to 1 ms	0.01 to 1 ms	Identical to the Nicolet EDX with Viking or Synergy software
4.1.5 Mode	Single or Train	Single or Train	Single or Train	Identical to the Nicolet EDX with Viking or Synergy software
4.1.6 Biphasic	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
4.2 Auditory Stimulator				
4.2.1 Type	Click, Pip, Burst	Click, Pip, Burst	Click, Pip, Burst	Identical to the Nicolet EDX with Viking or Synergy software
4.2.2 Intensity	0 to 139 dB pSPL	0 to 139 dB pSPL	0 to 139 dB pSPL	Identical to the Nicolet EDX with Viking or Synergy software
4.2.3 Polarity	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Condensation, Rarefaction, Alternating	Identical to the Nicolet EDX with Viking or Synergy software
4.2.4 Tone Frequency	125 to 8000 Hz	125 to 8000 Hz	250 to 8000 Hz	Identical to the Nicolet EDX with Viking or Synergy software
4.2.5 Click Duration	0.05 to 1 ms	0.05 to 1 ms	0.05 to 1 ms	Identical to the Nicolet EDX with Viking or Synergy software
4.2.6 Side	Left, Right, Both	Left, Right, Both	Left, Right, Both	Identical to the Nicolet EDX with Viking or Synergy software
4.2.7 Transducers	TDH 39, TIP 300, Bone Vibrator	TDH 39, TIP 300, Bone Vibrator	TDH 39, TIP 300, Bone Vibrator	Identical to the Nicolet EDX with Viking or Synergy software

5. EMG Application Modules				
Characteristic	**Natus Neurology, Inc. Synergy Focus (this submission)**	**CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)**	**CareFusion 209, Inc. Nicolet EDX with Viking (K112052)**	**Discussion of Differences**
5.1 Free Run Acquisition	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.2 Nerve Conduction Study (NCS)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.3 Stimulator Triggered	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.4 Signal Triggered Acquisition	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.5 Spontaneous Activity (SPA)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.6 Single Fiber EMG (SFEMG)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.7 Motor Unit Analysis	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.8 F-Wave	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.9 H Reflex (H-Wave)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
5.10 Sympathetic Skin Response (SSR)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software

6. Evoked Potential Application Modules

Characteristic	Natus Neurology, Inc. Synergy Focus (this submission)	CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)	CareFusion 209, Inc. Nicolet EDX with Viking (K112052)	Discussion of Differences
6.1 Somatosensory EP (SEP)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
6.2 Auditory EP (AEP)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
6.3 Visual EP (VEP)	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
6.4 P300	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
6.5 ERG	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
6.6 EOG	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
6.7 CNV	Yes	Yes	No	Identical to the Nicolet EDX with Synergy software
6.8 LED Goggles	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software

7. IOM Application Modules

Characteristic	Natus Neurology, Inc. Synergy Focus (this submission)	CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)	CareFusion 209, Inc. Nicolet EDX with Viking (K112052)	Discussion of Differences
7.1 IOM	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
7.2 Processed EEG	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software
7.3 MEP	Yes	Yes	Yes	Identical to the Nicolet EDX with Viking or Synergy software

8. Additional Features

Characteristic	Natus Neurology, Inc. Synergy Focus (this submission)	CareFusion 209, Inc. Nicolet EDX with Synergy System (K120979)	CareFusion 209, Inc. Nicolet EDX with Viking (K112052)	Discussion of Differences
8.1 Automatic Report Narrative Generation	Yes	Yes	No	Identical to the Nicolet EDX with Synergy software
8.2 Electrical Stimulus Automation	Yes	Yes	No	Identical to the Nicolet EDX with Synergy software

7 Summary of Non-Clinical Performance Testing Conducted for the Determination of Substantial Equivalence

Biocompatibility:

Natus has demonstrated the biocompatibility of all direct and indirect patient contacting material associated with the Synergy Focus through compliance with ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Test results have indicated that contacting materials complies with the standard and are safe for its intended use. There is one different contacting material than in the Nicolet EDX with Viking or Synergy Software. The probe tips of the Synergy Focus electrical stimulus probe with controls are gold plated whereas the Nicolet EDX probe tips are stainless steel. This has no impact on biocompatibility.

Software testing:

Similar to its predicate devices, Nicolet EDX with Viking or Synergy software, the Synergy Focus contains MODERATE level of concern software. The software was designed and developed according to a robust software development process, and was rigorously verified and validated consistent with the following guidelines:

- FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;
- FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and
- FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.

The test results demonstrated that the Synergy Focus complies with its predetermined specifications.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

The Synergy Focus was tested for electrical safety. Test results demonstrated that the Synergy Focus complies with the following standards:

- IEC 60601-1: 1988, Am1: 1991, Am2: 1995, Medical Electrical Equipment, Part 1: General Requirements for Safety.

Electromagnetic Compatibility (EMC) testing was conducted on the Synergy Focus according to the applicable standard. Test results indicated that the system complies with the following:

- IEC 60601-1-2: 2001, Am1: 2004, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

Performance Testing – Bench:

The Synergy Focus was tested to assess performance in accordance with requirements of the applicable performance standard. Test results demonstrated that the Synergy Focus met specifications and complies with the following standard:

- IEC 60601-2-40: 1998, Medical Electrical Equipment, Part 2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment.

Performance Testing – Animal & Clinical:
Animal testing and clinical testing were not needed to demonstrate safety and effectiveness.

8 Conclusion

The technological characteristics and performance data for the Synergy Focus system demonstrates that it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

Natus Neurology Incorporated
Mr. Shane T. Sawall
Manager, Regulatory Affairs
1850 Deming Way
Middleton, WI 53562

Re: K130346
Trade/Device Name: Natus Synergy Focus
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, JXE, IKN, OLT, GWJ, GWE, GXP
Dated: April 3, 2013
Received: April 5, 2013

Dear Mr. Sawall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: **K130346**

Device Name: **Natus Synergy Focus**

Indications For Use:

The Synergy Focus is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP), Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Synergy Focus may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The Synergy Focus is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Synergy Focus is intended to be used by a qualified healthcare provider.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
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(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number: K130346